No. 20-2402

UNITED STATES COURT OF APPEALS FOR THE SEVENTH CIRCUIT

UFCW Local 1500 Welfare Fund, et al.,
Plaintiffs-Appellants

v.

AbbVie Inc., et al.,
Defendants-Appellees

Appeal from the United States District Court
for the Northern District of Illinois
Case No. 19-cv-1873
The Honorable Judge Manish S. Shah

BRIEF FOR AMICI CURIAE STATES OF WASHINGTON, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, IDAHO, ILLINOIS, MAINE, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, NEBRASKA, NEW MEXICO, NEW YORK, NORTH CAROLINA, OREGON, RHODE ISLAND, VIRGINIA, AND WISCONSIN SUPPORTING PLAINTIFFS-APPELLANTS AND REVERSAL

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INTEREST OF AMICI CURIAE

Amici are the States of Washington, California, Colorado, Connecticut, Delaware, Idaho, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, New Mexico, New York, North Carolina, Oregon, Rhode Island, Virginia, and Wisconsin. Amici States file this brief under Fed. R. App. P. 29(a)(2). The States have a strong interest in this case both as healthcare consumers and government antitrust enforcers. The States spend millions annually on prescription drugs by reimbursing patients' purchases through Medicaid and other programs. Patients, employers, and insurers within our jurisdictions spend billions of dollars on prescription drugs. Biologic drugs like Humira represent a large and growing share of that spending. Anticompetitive conduct that raises biologic drug prices and eliminates competitive choice substantially harms the States and their residents.

The States also enforce federal and state antitrust laws.[1] S*ee* 15 U.S.C. § 15c(a)(1). The States have a long history of actively challenging anticompetitive conduct in the pharmaceutical industry, and have a strong interest in the development and proper application of the antitrust laws to conduct in this

[1] Amici States note here that dismissal of federal antitrust claims does not automatically require dismissal of state antitrust claims challenging the same conduct. Not all state antitrust statutes mirror federal antitrust law and some have been explicitly recognized as broader than federal law. *E.g.*, *In re Cipro Cases I & II*, 348 P.3d 845, 872 (Cal. 2015) ("The Cartwright Act is broader in range and deeper in reach than the Sherman Act.") (cleaned up). Further, some states have enacted laws specifically addressing certain forms of anticompetitive conduct. For example, a California statute that became effective January 1, 2020, creates a presumption that certain reverse-payment agreements are anticompetitive and, where that presumption is not rebutted, imposes a civil penalty. *See Ass'n for Accessible Med. v. Becerra*, No. 20-15014, 2020 WL 4251776, at *1 & n.1 (9th Cir. July 24, 2020) (describing the statute).

industry. The States offer this amicus brief to address the district court's troubling misapplication of *Actavis* and the rule of reason to AbbVie's agreements and to urge the Seventh Circuit against unduly narrowing the sham petitioning exception to *Noerr-Pennington*.

SUMMARY OF ARGUMENT

The district court relied on flawed analyses that—if affirmed—will embolden anticompetitive practices in the pharmaceutical industry and hamstring antitrust enforcers.[2] Its *Actavis* analysis contained three particularly troubling flaws.

First, it held that any agreements granting market entry before patent expiration are automatically immune from antitrust scrutiny. This directly contradicts the Supreme Court's teaching that patent settlements enjoy no presumption of legality. *See FTC v. Actavis*, 570 U.S. 136, 147–48 (2013). The decision below created such a presumption, and did so by resurrecting the discredited "scope of the patent" test. *See In re Humira (Adalimumab) Antitrust Litig.*, No. 19-cv-1873, 2020 WL 3051309, at *20 (N.D. Il. June 8, 2020) (declaring that AbbVie's Humira agreements at worst "preserved an anticompetitive status quo" created by AbbVie's Humira patents).

Second, it relied on unwarranted factual and legal assumptions about procompetitive effects. The district court announced, for example, that the challenged agreements "deliver value to consumers" and "increased competition." *Id.* at *20–21. Relying upon disputed facts that contradict the complaint's allegations is improper on a Fed. R. Civ. P. 12(b)(6) motion. Moreover, the challenged agreements caused harm by eliminating the possibility that AbbVie's rivals could enter the U.S. market even earlier than their agreed-upon entry dates.

[2] Amici States' brief does not address the other issues decided below, including issues pertaining to the alleged market allocation claim or antitrust injury. This brief should not be construed as agreeing or disagreeing with those decisions.

Merely allowing them to enter the U.S. market before AbbVie's disputed patents expired does not eliminate that harm. The district court also assumed without basis that allowing rivals to enter in Europe created cognizable procompetitive effects despite the complaint alleging harm only in the United States.

Third, the district court gave undue weight to the public policy goal of "encouraging patent litigants to settle worldwide patent disputes." *In re Humira*, 2020 WL 3051309, at *21. *Actavis* specifically rejected the argument that any public policy favoring "the desirability of settlements" could trump the application of antitrust law to potentially harmful patent settlements. *Actavis*, 570 U.S. at 158.

In short, the decision below represents a frontal assault on *Actavis* and enforcers' long campaign against anticompetitive conduct in the pharmaceutical industry. Allowing errors like these to persist and gain traction would jeopardize effective antitrust enforcement in this industry while drug prices continue to soar. Amici States urge this Court to correct these errors and reverse the decision below dismissing the Plaintiffs-Appellants' Sherman Act § 1 claims.

Amici States also urge this Court to apply *California Motor Transport* rule to Plaintiffs-Appellants' Section 2 claims. That more flexible, holistic analysis is the appropriate standard for serial sham petitioning cases like this one.

ARGUMENT

I. The District Court Misapplied *Actavis* to AbbVie's Humira Agreements.

A. Agreements granting entry before patent expiration are not automatically free from antitrust scrutiny.

In the decision below, the district court acknowledged that AbbVie's Humira settlements allegedly included large, unjustified payments from AbbVie to its rivals. *In re Humira*, 2020 WL 3051309, at *20. It found that AbbVie granted these rivals licenses to enter European markets in 2018, and acknowledged that risk-free entry was worth hundreds of millions of dollars to them. *Id.* In exchange, the rivals agreed to drop their challenges to AbbVie's U.S. patents and delay entering the U.S. market until 2023. *Id.* These findings suffice to state prima facie case under *Actavis*. *See Actavis*, 570 U.S. at 158.

Yet the district court incorrectly held that AbbVie's Humira agreements were "specifically permitted by *Actavis*" as a matter of law and dismissed the Plaintiffs-Appellants' Section 1 claims. *See In re Humira*, 2020 WL 3051309, at *21. On the district court's reading, *Actavis* not only "approved of" agreements granting entry before patent expiration, *In re Humira*, 2020 WL 3051309, at *8, but fully removes them from antitrust review, notwithstanding the alleged purpose or effect of the agreements. *Id.* at *20.

The argument that *Actavis* immunizes agreements granting entry before patent expiration from antitrust review does not withstand scrutiny. *Actavis* itself considered a reverse-payment agreement that allowed rivals to enter the market five years before the challenged patent expired and concluded that these

agreements have the "potential for genuine adverse effects on competition." *Actavis*, 570 U.S. at 145, 153. It explained that the "payment in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent litigation were to continue and the patent were held invalid or not infringed by the generic product." *Id.* at 153–54. "Continued litigation, if it results in patent invalidation or a finding of noninfringement, could cost the patentee . . . revenues . . . that then would flow in large part to consumers in the form of lower prices." *Id.* at 154. On the other hand, "payment in return for staying out of the market . . . keeps prices at patentee-set levels, potentially producing the full patent-related . . . monopoly return while dividing that return between the challenged patentee and the patent challenger." *Id.* The result: the "patentee and the challenger gain; the consumer loses." *Id.*

Actavis thus rejected a near-immunity rule, instead analyzing the potential anticompetitive effects of settlement agreements. As the Federal Trade Commission recently explained, *Actavis* did not "state a general rule that removes settlement agreements from antitrust scrutiny." *1-800 Contacts, Inc.*, 166 F.T.C. 274, 287 (2018).[3] Rather, *Actavis* clarified that "a reverse payment's legality depends mainly on its economic substance, not its form." *FTC v. AbbVie Inc.*, No. 18-2621, 2020 WL 5807873, at *17 (3d Cir. Sept. 30, 2020).

[3] *Available at* https://www.ftc.gov/system/files/documents/commission_decision_volumes/volume-166/vol166complete.pdf.

The district court cites *Actavis*'s explanation that litigants could safely settle by allowing an alleged infringer to enter the market before the challenged patent expires. *In re Humira*, 2020 WL 3051309, at * 8 ("*Actavis* . . . approved of settlements where the only reverse payment is an agreement permitting the alleged infringer to 'enter the patentee's market prior to the patent's expiration'") (quoting *Actavis*, 570 U.S. at 158). But that language addressed agreements lacking a payment to the rival in exchange for delayed market entry. *Actavis*, 570 U.S. at 158. The Supreme Court was explaining that litigants could settle "without the patentee paying the challenger to stay out" before the agreed-to entry date. *Id. Actavis* "does not hold that an early entry date (relative to the patent expiration date) is *automatically* procompetitive." *Staley v. Gilead Sci., Inc.*, 446 F. Supp. 3d 578, 610 (N.D. Cal. 2020). Courts must examine the "cumulative effect of the factual allegations" in the complaint, like the existence of a reverse payment in exchange for delayed entry as alleged here. *Picone v. Shire PLC*, No. 16-cv-12396, 2017 WL 4873506, at *12 (D. Mass Oct. 20, 2017) (quoting *Ocasio-Hernandez v. Fortuno-Burset*, 640 F.3d 1, 14 (1st Cir. 2011)); *see Sergeants Benevolent Ass'n Health & Welfare Fund v. Acta Vis, PLC* No. 15-cv-6549, 2016 WL 4992690, at *13 (S.D.N.Y. Sept. 13, 2016) (explaining that "patent holders could still lawfully settle with an alleged infringer" after *Actavis* but that "courts must determine the anticompetitive effect of such settlements by considering traditional antitrust factors[.]") (internal quotation marks omitted).

The district court here did not conclude that the Humira agreements as alleged lacked anticompetitive effects. *See In re Humira*, 2020 WL 3051309, at *20–21 (finding that the complaint alleged payment in exchange for delayed U.S. entry). Instead, it held that it could not consider the anticompetitive effects of the whole exchange based on its view that *Actavis* precludes antitrust review of agreements that grant entry before patent expiration. This approach turns *Actavis* on its head and threatens to nullify its core holding. By calling any combination of agreements granting market entry before expiration of disputed patents permissible and procompetitive, it assumes any restraints within that scope—like inducing a rival to withdraw efforts to enter the market even earlier—are acceptable. That same faulty logic was the basis for the scope of the patent test that *Actavis* overruled.

1. Courts have rejected claims that Actavis *categorically exempts certain forms of settlement agreement from antitrust scrutiny.*

The district court's flawed analysis contrasts with recent decisions emphatically rejecting arguments that *Actavis* creates safe harbors for certain types of agreement. *See, e.g.*, *In re Lipitor Antitrust Litig.*, 868 F.3d 231 (3d Cir. 2017); *Shire*, 2017 WL 4873506; *Staley*, 446 F. Supp. 3d 578; *AbbVie*, 2020 WL 5807873. For example, in *Lipitor*, Pfizer released a damages claim against its generic rival in exchange for $1 million and the rival's commitment to delay launching its generic version of Pfizer's drug Lipitor. *In re Lipitor*, 868 F.3d at 253. The plaintiffs alleged that the damages claim was worth significantly more than $1 million—likely hundreds of millions of dollars. *Id.* The defendants argued that this settlement was "no more than the sort of commonplace settlement that the Supreme Court excluded

from antitrust scrutiny" in *Actavis*. *Id.* at 254. The Third Circuit disagreed, emphasizing that the defendant's proposed safe harbor would permit parties to "shield their settlements from antitrust review" simply by adopting superficial changes such as a "token payment" by the generic rival. *Id.* at 258. That outcome "simply cannot be squared with *Actavis.*" *Id*. It further emphasized that the defendant's attempt to label their agreement "commonplace" could not "withstand . . . plaintiffs' plausible allegations and the reasonable inferences arising therefrom." *Id.*; *see also id.* at 256 ("To plausibly allege an unjustified reverse payment, an antitrust plaintiff need only allege the absence of a 'convincing justification' for the payment."). The Third Circuit thus reversed the district court's dismissal and remanded for further proceedings. *Id.* at 274.

Similarly, *Shire* considered allegations that Shire compensated its generic rivals with a promise not to launch its own authorized generic and by charging them a below-market royalty rate in exchange for delayed entry. *Shire*, 2017 WL 4873506, at *3. The *Shire* defendants moved to dismiss, arguing that the court could not consider the effects of the below-market royalty since it fit within the category of "permissible settlements." *Id.* at *11. They relied on language in *Actavis* suggesting that a settlement granting entry before patent expiration, without a reverse payment, would not likely raise antitrust issues. In denying the defendants' motion to dismiss, the *Shire* court observed that a below-market royalty rate could compensate a rival and thereby incentivize it to drop a patent challenge, which is the "sort of anticompetitive harm that concerned the Supreme Court" in *Actavis*. *Id.*

at *12. It then rejected the defendants' characterization of *Actavis* as holding that "a below market royalty-rate is completely insulated from the Court's consideration[.]" *Id.* Instead, the court explained that it was required to consider the effects of the whole agreement as alleged. *Id.* The court held that the complaint plausibly alleged competitive harm under *Actavis*. *Id.*

In *Staley*, the district court permitted claims to proceed where the patent holder allegedly compensated a rival with most-favored-entry rights, again refusing to exempt a settlement from scrutiny based on its form. *Staley*, 446 F. Supp. 3d at 612. There, Gilead paid its generic rival Teva through two deals that gave Teva the right to move its market entry dates up if Gilead granted anyone else an earlier date. *Id.* at 590. Separate terms prevented Gilead from offering others entry dates less than six weeks (or in another agreement, six months) after Teva's. *Id.*

Gilead argued that the most-favored-entry terms could not constitute an anticompetitive reverse payment because those terms were "actually procompetitive in nature," citing *Actavis*. *Id.* at 610. The district court rejected Gilead's characterization of *Actavis*, noting that *Actavis* did not hold that early entry relative to patent expiration alone rendered an agreement "automatically procompetitive." *Id.* at 610. In context, the most-favored-entry terms allegedly induced Teva to delay its entry into the market and dissuaded other generics from following in Teva's wake, thus guaranteeing Gilead's monopoly for the next few years. *Id.* at 610–12. The court held that those allegations sufficed to defeat a motion to dismiss. *Id.* at 612.

Finally, *AbbVie* reversed dismissal of a reverse-payment claim by the Federal Trade Commission based on an agreement allowing a rival to enter the market for one drug, TriCor, in exchange for the rival's agreement to delay entering the market for another, AndroGel. AbbVie allegedly agreed to authorize Teva to sell a generic version of TriCor and to supply that generic version to Teva. *AbbVie*, 2020 WL 5807873, at *17. In exchange, Teva agreed to drop its challenge to AbbVie's AndroGel patent and defer competing with AndroGel. *Id.*

The Third Circuit reversed dismissal, finding that these allegations stated a plausible claim under *Actavis*. First, it held that the district court's insistence on analyzing the TriCor and AndroGel agreements separately was error because it "elevate[d] form over substance" and "contradicts pleading law." *Id.* at *19. Because the FTC had alleged the two agreements were linked, the district court "had to accept that allegation as true." *Id.* Next, the Third Circuit rejected the district court's conclusion that the agreements were not reverse payments because AbbVie was not paying Teva directly. *Id.* It explained that the TriCor agreement, as alleged, transferred value to Teva without a cognizable justification, which constitutes a reverse payment under *Actavis* and *King Drug*. *Id.*

Finally, the Third Circuit criticized the district court's conclusion that the AndroGel settlement was "procompetitive as a matter of law." *Id.* It acknowledged that an agreement that simply "allows a generic company to enter a market before patent expiration" standing alone is likely to be procompetitive. *Id.* But that only holds where the patent holder did not pay its rival to delay entry. *Id.* Because the

complaint alleged a payment for delayed entry, and because "pay-for-delay is anticompetitive even if the delay does not continue past patent expiration," the court held it was error to conclude the agreements benefitted competition as a matter of law. *Id.*

These cases lay bare the errors in the decision below. As the Third Circuit explained, *Actavis* does not insulate agreements from antitrust scrutiny merely because they resemble a so-called "commonplace" form of settlement on the surface, nor can courts ignore allegations in the complaint when evaluating a motion to dismiss. *Lipitor*, 868 F.3d at 257-58. Yet here, the district court declared AbbVie's Humira agreements were "permissible early entry settlement[s]," *In re Humira*, 2020 WL 3051309, at *21, and exempted them from further scrutiny despite plausible allegations conflicting with that characterization. It thereby insulated from consideration settlement terms that the court agreed transferred value from AbbVie to its rivals in exchange for perpetuating AbbVie's monopoly. *Id.* at *20–21; *cf. Shire*, 2017 WL 4873506, at *12. And it reached that conclusion by assuming that granting entry before patent expiration is automatically procompetitive, contrary to *Actavis*, and by erroneously ignoring the allegations in the complaint.

2. The district court's approach will further embolden pharmaceutical companies to fashion illegal settlements to more creatively evade scrutiny.

Pharmaceutical companies responded to years of enforcement efforts by the States and other enforcers by fashioning new settlement forms to evade scrutiny while continuing to compensate generic rivals with shared monopoly profits in exchange for delaying competition. Today, large cash payments to a generic rival

are unusual. *See* Michael A. Carrier, *Solving the Drug Settlement Problem: The Legislative Approach*, 41 Rutgers L.J. 83, 98 (2009). Instead, settlement terms are more likely to include complex and difficult-to-detect exchanges. *See* Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 Chi.-Kent J. Intell. Prop. 249, 273 (2019). For example, the cases highlighted above considered challenges to settlement agreements featuring "no-authorized-generic" commitments, releases of large damages claims for nominal payment, below-market royalties, most-favored entry terms, and a supply agreement for a separate product. These and other potentially harmful forms of payment may both delay initial entry and also discourage follow-on competitors, and continue to proliferate. *See* Laura Karas, Gerard F. Anderson, & Robin Feldman, *Pharmaceutical "Pay-for-Delay" Reexamined: A Dwindling Practice or a Persistent Problem?*, 71 Hastings L.J. 959, 965–66 (2020). Indeed "there is good reason to believe that anticompetitive pay-for-delay agreements continue to be reached in the United States post-*Actavis*" and in increasingly creative guise. *Id.* at 966.

It is therefore imperative that courts reject formalistic interpretations of *Actavis*. Altering the form of an anticompetitive reverse-payment agreement does not lessen its harmful impact. Categorically immunizing some settlements from antitrust scrutiny will only encourage further artful collusion among drug companies without generating any procompetitive benefits. If "companies could avoid liability for anticompetitive reverse payments simply by structuring them as two separate agreements . . . *Actavis* would become a penalty for bad corporate lawyering instead

of anticompetitive conduct." *AbbVie*, 2020 WL 5807873, at *19. This court should avoid this illogical result by applying the functional analysis *Actavis* demands and reversing the decision below.

B. Procompetitive effects do not justify dismissal here because they depend on disputed facts and are not linked to the restraint alleged.

The district court committed a second analytical misstep by prematurely concluding that AbbVie's Humira settlements created procompetitive effects. The effects it highlighted all derive from the market entry dates the agreements granted AbbVie's rivals. The district court identified no "avoided litigation costs or fair value for services" that might justify AbbVie's payments. *See Actavis*, 570 U.S. at 156. Instead, it declared variously that the agreements "deliver value to consumers," "increased competition," or at worst "preserved an anticompetitive status quo" because they allowed AbbVie's rivals to enter in the United States and Europe before AbbVie's patents expired. *In re Humira*, 2020 WL 3051309, at *20–21; *see also id.* at *21 (declaring that "consumers won and the market for Humira (and its generics) became more competitive" because of the challenged agreements).

1. The district court erred in concluding that procompetitive effects justified the challenged agreements at the pleading stage.

Relying on purported procompetitive effects to dismiss the complaint was error for two reasons. First, "*Actavis* does not require antitrust plaintiffs to come up with possible explanations for the reverse payment and then rebut those explanations in response to a motion to dismiss. The Supreme Court clearly placed the onus of explaining or justifying a large reverse payment on *antitrust defendants*." *Lipitor*, 868 F.3d at 256–57. Plaintiffs can meet their pleading burden "without describing

in perfect detail the world without the reverse payment . . . or preempting every possible explanation for it." *AbbVie*, 2020 WL 5807873, at *17. Simply identifying potential justifications for the agreements is not a basis for dismissing the complaint because defendants bear the burden on that issue.

Second, these specific conclusions rested on disputed facts that cannot be resolved as a matter of law on a motion to dismiss. *See* Appellants' Br. 24–25. The court was required to accept the alleged facts as true and draw all reasonable inferences in the Plaintiffs-Appellants' favor. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). An antitrust complaint "does not need detailed factual allegations" to survive a Fed. R. Civ. P. 12(b)(6) motion. *Bell Atlantic Corp. v. Twombly,* 550 U.S. 544, 555 (2007); *see also In re Lipitor*, 868 F.3d at 254–55 (reversing dismissal of a reverse-payment claim because the district court wrongly applied a "heightened pleading standard" contrary to *Twombly* and *Iqbal*). A complaint is plausible and raises "a reasonable expectation that discovery will reveal evidence of an illegal agreement" even if the district court believes "that actual proof of those facts is improbable, and that a recovery is very remote and unlikely." *Twombly,* 550 U.S. at 556 (quotation marks omitted). The district court overstepped its role at this stage of the case by making factual findings in the defendants' favor, as its decision characterizing the agreements as net beneficial demonstrates. The Plaintiffs-Appellants deserve an opportunity to disprove these purported justifications through discovery.

2. None of the procompetitive effects the district court identified offset the harm alleged.

Even if the effects the court identified were substantiated, courts cannot credit procompetitive effects unless the defendant can "articulate the specific link between the challenged restraint and the purported justification." *Polygram Holding, Inc.*, 136 F.T.C. 310, 347 (2003), *aff'd Polygram Holding, Inc. v. FTC*, 416 F.3d 29 (D.C. Cir. 2005). The district court erred because the procompetitive effects it identified are neither cognizable nor linked to the harm alleged.

Actavis forecloses the district court's conclusion that the challenged agreements are procompetitive (or competitively neutral) simply because they allow AbbVie's rivals to enter the U.S. market before AbbVie's patents expire. Reverse-payment agreements harm competition by eliminating the risk that the patent holder may face competition well before its patent's expiration date. *Actavis*, 570 U.S. at 157–58. In other words, even if an agreement allows pre-expiration market entry, it can still be anticompetitive because the rival may have entered the market even sooner in the absence of the agreement, generating competition far earlier. Courts therefore cannot assume that patents justify an absolute monopoly extending to the expiration of a disputed patent and automatically credit entry before that as procompetitive. *See AbbVie*, 2020 WL 5807873 at *19. Thus, the U.S. entry dates themselves do not create cognizable procompetitive effects.

The European entry dates fare no better. The district court claims that its holding did not depend on justifying harm in one market with benefits in another. *In re Humira*, 2020 WL 3051309, at *21; *see also United States v. Topco Assocs.*, 405

U.S. 596, 611 (1972) ("If a decision is to be made to sacrifice competition in one portion of the economy for greater competition in another portion this too is a decision that must be made by Congress and not by private forces or by the courts."). But its decision turned on finding that the agreement terms granting entry in Europe were "permissible under *Actavis*," because they "deliver[ed] value to consumers." *In re Humira*, 2020 WL 3051309, at *20–21. Likewise, the district court's basis for distinguishing the agreements here from the reverse-payment agreements in *King Drug* was that "consumers won and the market for Humira . . . became more competitive" when AbbVie agreed to let its rivals to enter "European and U.S. markets earlier than they might have been able to otherwise." *Id.* at *21.

Here, the complaint identified Humira sold in the United States as the relevant antitrust market. *Id.*, at *7. And for good reason: regulatory barriers prevent AbbVie or its rivals from selling their European biologics to U.S. consumers. *See id.* at *3–4 (describing the FDA approval process for biologics). As a result, the alleged competition in Europe cannot have benefitted consumers in the United States. The district court thus failed to link this ostensible benefit to the restraint at issue: delayed competition in the United States securing AbbVie's U.S. monopoly and guaranteeing U.S. consumers pay more for Humira for many years.

Indeed, the U.S. market remains monopolized today. According to the complaint, the "cost of Humira to treat arthritis in the U.S. remains 50% more expensive than the cost of the same treatment in Spain." *Id.* at *7. Since the complaint was filed, AbbVie has continued to ratchet up the price of Humira in the United States. This

year it increased prices 7.4%, following a 6.2% increase in 2019. Noam N. Levey, *Vaccine maker got $1 billion from taxpayers. Now it's boosting drug prices*, L.A. Times (Sept. 14, 2020), https://www.latimes.com/politics/story/2020-09-14/drug-maker-got-1-billion-from-taxpayers-boosting-prices.

AbbVie's public financial disclosures likewise show that AbbVie's U.S. Humira revenues continue to grow in the absence of biosimilar competition. In 2017, the year before AbbVie entered into the Humira agreements, it reported approximately $12.4 billion in Humira revenue in the United States. AbbVie Inc., Annual Report (From 10-K) at 31 (Feb. 21, 2020), https://investors.abbvie.com/sec-filings?items_per_page=10&page=9. At the time, that accounted for 67% of its total Humira revenue. *Id.* As of February 2020, AbbVie's U.S. revenues had grown to $14.9 billion annually, now over 77% of its total Humira revenue. *Id.* AbbVie attributes its declining international Humira revenue to "direct biosimilar competition in certain international markets." *Id.* at 32; *see also* AbbVie Inc., Quarterly Report (Form 10-Q) at 36 (Aug. 4, 2020), https://investors.abbvie.com/sec-filings?items_per_page=10&page=0. In recent quarters, growth in AbbVie's U.S. Humira revenue has roughly made up for revenue lost to biosimilar competitors abroad. *Id.* at 35 (showing only 0.7% decline in total Humira revenue year-over-year for the quarter ending June 30, 2020). This suggests AbbVie's alleged willingness to share its European profits with rivals to forestall U.S. competition was not only plausible—it has succeeded at enriching AbbVie at the expense of consumers in the United States.

C. Contrary to the Supreme Court's directive in *Actavis*, the decision below gave undue weight to the desirability of encouraging settlement and wrongly shifted the burden of proof to plaintiffs.

Amici States address one final error in the district court's *Actavis* analysis: its improper emphasis on pro-settlement policy as an alternative reason to uphold the challenged Humira agreements. After describing its reasons for concluding that *Actavis* immunizes AbbVie's agreements from rule-of-reason scrutiny, the court identified "a broader reason to uphold these agreements under antitrust review: encouraging patent litigants to settle worldwide patent disputes." *In re Humira*, 2020 WL 3051309, at *21. This was wrong for two reasons.

First and more importantly, the Supreme Court specifically rejected elevating "the desirability of settlements" over competition concerns when assessing patent settlements. *Actavis*, 570 U.S. at 158. Under *Actavis*, a policy of encouraging settlement cannot justify an otherwise anticompetitive agreement. If the agreements were anticompetitive reverse-payment deals, deference to that policy concern cannot save them. The district court overstepped its role by substituting its own view on the policy balance struck by federal antitrust law for that of the Supreme Court.

Second, the district court improperly placed the burden of disproving this justification on the plaintiffs. Because the court conceded that the complaint alleged "particular circumstances" taking these agreements "outside the norm," such that "worldwide patent disputes" in general would not become unworkable, it was error to discredit those allegations and require the complaint to "elaborate." *In re Humira*, 2020 WL 3051309, at *21. Requiring the complaint to anticipate and plead

allegations to negate the defendants' defenses contradicts established precedent placing the burden on defendants to prove procompetitive justifications. *See Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018).

II. The Seventh Circuit Should Join the Majority of Courts of Appeals in Applying *California Motor Transport* to Serial Sham Petitioning.

Plaintiffs-Appellants alleged that AbbVie asserted "swaths of invalid, unenforceable, or noninfringed patents" in adjudicative proceedings with the intent and effect of imposing costs and delays on its biosimilar rivals. *In re Humira*, 2020 WL 3051309, at *9. It sought exclusion not through recognition of legitimate patent rights but through raising its rivals' costs by forcing them to invest time and money rebutting allegedly worthless arguments. *Id.* Rather than considering the overall exclusionary effects of this conduct, the district court limited its analysis to a subset, concluding that the rest was protected by *Noerr-Pennington* immunity. *See In re Humira*, 2020 WL 3051309, at *14. This Court should join the majority of circuits and conclude that allegations of serial sham petitioning in adjudicative settings adequately plead a Sherman Act § 2 violation, without requiring allegations that every claim was objectively baseless.

The *Noerr-Pennington* doctrine immunizes from antitrust liability "mere attempts to influence the Legislative Branch for the passage of laws or the Executive Branch for their enforcement." *Cal. Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508, 510 (1972). Because abusing government processes offers a monopolist a cheap, effective tool for excluding rivals, the Supreme Court has long recognized that attempts to "interfere directly with the business relationships of a

competitor" hidden beneath a pretextual attempt to influence the government deserve no immunity. *E.R.R. Presidents Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127, 144 (1961).

Where the antitrust defendant allegedly brought several repetitive petitions in adjudicative proceedings, most Courts of Appeals continue to employ the flexible, holistic analysis established by the Supreme Court in *California Motor Transport*.[4] There, the Court held "a pattern of baseless, repetitive claims" could show that "administrative and judicial processes have been abused" such that *Noerr-Pennington* immunity does not apply. *Cal. Motor Transport*, 404 U.S. at 513. The alternative approach exempts from *Noerr-Pennington* immunity only those specific petitions shown to be objectively baseless, such that "no reasonable litigant could realistically expect success on the merits." *Prof'l Real Estate Invs., Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993) ["*PRE*"].

Although the Supreme Court left some ambiguity about reconciling the existing *California Motor Transport* standard with *PRE*, the better view limits *PRE* to cases alleging a single sham suit and maintains *California Motor Transport* as the

[4] *USS-POSCO Indus. v. Contra Costa Cty. Bldg. & Constr. Trades Council, AFL-CIO*, 31 F.3d 800 (9th Cir. 1994); *PrimeTime 24 Joint Venture v. Nat'l Broad. Co.*, 219 F.3d 92 (2d Cir. 2000); *Waugh Chapel S., LLC v. United Food & Commercial Workers Union Local 27*, 728 F.3d 354 (4th Cir. 2013) (analyzing *Noerr-Pennington* sham exception under the National Labor Relations Act); *Hanover 3201 Realty, LLC v. Village Supermarkets, Inc.*, 806 F.3d 162 (3d Cir. 2015), *cert denied*, 136 S. Ct. 2451 (2016). *See also Livingston Downs Racing Ass'n Inc. v. Jefferson Downs Corp.*, 192 F. Supp. 2d 519 (M.D. La. 2001); *Total Renal Care, Inc. v. W. Nephrology & Metabolic Bone Disease, P.C.*, No. 8-cv-00513, 2009 WL 2596493 (D. Colo. Aug. 21, 2009).

standard for evaluating serial sham petitioning. As the Ninth Circuit has explained, the two cases apply to "different situations" and deal with different levels of potential competitive harm. *USS-POSCO*, 31 F.3d at 810–11 (9th Cir. 1994). For one thing, "the filing of a whole series of lawsuits and other legal actions without regard to the merits has far more serious implications than filing a single action, and can serve as a very effective restraint on trade." *Id.* at 811. The cost of "filing an additional sham complaint is negligible, but the cost of defending against the complaint is high in comparison." Susan A. Creighton et al., *Cheap Exclusion*, 72 Antitrust L.J. 975, 993 (2005).

For another, serial petitioning involves a "more complex fact sets." *Hanover 3201 Realty,* 806 F.3d at 180. In a single suit case, the court must decide whether a single petition constituted an abuse of process. Thus the objective merit of that single action allows the court to conclude that the "action is perforce not a sham." *USS-POSCO*, 31 F.3d at 811. But in a serial petitioning case, the court is presented with more information and therefore "sits in a much better position to assess whether the defendant has misused the government process to curtail competition." *Hanover 3201 Realty*, 806 F.3d¶ at 180. The *California Motor Transport* approach properly directs courts to weigh this broader range of evidence in identifying an anticompetitive abuse of process.

Finally, the Seventh Circuit's decision in *U.S. Futures Exchange LLC v. Board of Trade of the City of Chicago, Inc.* does not foreclose applying *California Motor Transport* to the type of conduct challenged here. *U.S. Futures Exchange LLC v.*

Board of Trade of the City of Chicago, Inc., 953 F.3d 955 (7th Cir. 2020). That case addressed "a *single* legislative proceeding," not a "wide-ranging 'pattern." *Id.* at 965. By contrast, the conduct alleged here "involves adjudicative proceedings" including "patent infringement actions in federal district court." *In re Humira*, 2020 WL 3051309, at *11. Further, the complaint alleges that "some of the assertions AbbVie made . . . were objectively baseless." *Id.* at *13. *U.S. Futures* thus addresses significantly different conduct and should not govern here. *See* Appellants' Br.41-44. Applying the *PRE* test in cases like this one inappropriately constrains the analysis and invites anticompetitive abuse of process.

Maintaining the flexibility afforded under *California Motor Transport* is particularly important in the pharmaceutical context. The complex regulatory schemes that govern generic and biosimilar drug approvals, and the patent system, present incumbent monopolists with many opportunities to cheaply impose burdensome proceedings on their rivals. As this case demonstrates, the growth of the biologics market will exacerbate this problem because of the staggering number of patent filings claiming some of these drugs. The adverse consequences of immunizing such repeated petitioning activity and enforcement actions short of adjudicative decisions on the merits are already known and will only exponentially increase. AbbVie's petitioning and subsequent settlements have allowed it to continue aggressively increasing prices making Humira one of the "most expensive medications for patients, consumers, and taxpayers in the United States." Rep. Carolyn B. Maloney, H. Comm. on Oversight & Reform, 116th Cong., Notice of

Intent to Issue a Subpoena to AbbVie Inc. 1 (Sept. 1, 2020).[5] This Court should heed these risks and clarify that district courts may assess the full range of evidence of abusive conduct in cases alleging serial adjudicative petitioning in accord with *California Motor Transport*.

CONCLUSION

Decisions like the one below threaten to undermine effective antitrust enforcement against collusive agreements in the pharmaceutical industry by exempting anticompetitive agreements from judicial review. Many of the same companies paying their rivals to delay entry also routinely abuse government processes by using serial sham petitions to deter competitive entry. These anticompetitive practices persist despite years of antitrust enforcement effort, limiting incentives to innovate and costing the States and their residents dearly in overcharges.

For the reasons described above the States urge this Court to reverse the decision below.

[5] *Available at* https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2020-09-01%20AbbVie%20Subpoena%20Memo.pdf.

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I hereby certify that:

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2. This brief complies with Circuit Rule 29 because it contains 6,233 words, excluding parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

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